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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/539,409

06/17/2005

Reinhold Buck

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22852

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09/27/2010

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

BASS, DIRK R

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,409	Applicant(s) BUCK ET AL.	
	Examiner DIRK BASS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15,29-31 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15,29-31 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/20/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's response filed August 20, 2010 is acknowledged. Claims 1 and 15 are amended, claims 16-28, 32 are cancelled, and claim 33 is newly added. Claims 1-15, 29-31, and 33 are pending and further considered on the merits.

Response to Amendment

In response to applicant's amendment, the examiner modifies the grounds of rejection set forth in the office action dated February 23, 2010.

Claim Rejections - 35 USC § 102/103

1. **Claims 1, 3-10, and 12-13** are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kim et al., USPA 2004/0167237 (Kim) as evidenced by Gorsuch et al., US 6802820 (Gorsuch).
2. Regarding claim 1, Kim discloses an asymmetric hollow fiber membrane (abstract, ¶ 0056) comprised of at least one hydrophobic polymer and at least one hydrophilic polymer (Example 1, ¶ 0188), wherein said membrane allows passage of molecules having a molecular weight of up to 45kD with a sieving coefficient of 0.1-1.0 in the presence of whole blood, wherein the membrane allows the retention of a portion of albumin in the presence of whole blood (Table 1, Example 1).
3. Kim is silent as to the molecular weight exclusion limit of about 200kD. Nevertheless, Kim discloses a hollow fiber membrane with the same preferred structure as contained in Applicant's claims/specification; therefore, it is inherent that said membrane has the molecular weight exclusion limit of about 200kD (See MPEP 2112).
4. In the alternative, molecular weight exclusion limits are deemed to be result effective variables as evidenced by Gorsuch (fig. 7). Gorsuch provides evidence in figure 7 that size exclusion limits can be easily manipulated based on the test methods used to determine the size exclusion limits and a multitude of possible structural and operational limitations can be envisaged based on these characteristics. Therefore, at the time of invention it would have been obvious to a routineer in the art to modify the molecular weight exclusion limit of Kim since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art (MPEP 2144.05, Section II, Part B).

5. Regarding claim 3, Kim discloses a membrane wherein said at least one hydrophobic polymer is present in an amount of 50-80% by weight (¶ 0068-0071, 0138-0139).
6. Regarding claim 4, Kim discloses a membrane wherein said at least one hydrophilic polymer is present in an amount of 20-50% by weight (¶ 0100, 0192).
7. Regarding claims 5 and 6, Kim discloses a membrane wherein the hydrophobic polymer is polysulfone (¶ 0051) and the hydrophilic polymer is polyvinylpyrrolidone (¶ 0040).
8. Regarding claim 7, Kim discloses a membrane wherein said membrane has a 3 layer asymmetric structure (fig. 1).
9. Regarding claim 8, Kim discloses a membrane wherein a separation layer is present in the inner most layer of the hollow fiber (REF a, fig. 1).
10. Regarding claim 9, Kim discloses a membrane wherein the separation layer has a thickness of less than 0.5 μm (¶ 0057).
11. Regarding claim 10, Kim discloses a membrane wherein the separation layer contains pore channels (¶ 0056).
12. Regarding claim 12, Kim does not explicitly disclose the sieving coefficient for IL-6 in whole blood. However, Kim discloses a membrane that has a $\beta 2$ microglobulin (MW 11kD) sieving coefficient of 1 and $\alpha 1$ microglobulin (MW 33kD) sieving coefficient in the range of 0.16-.024. Therefore, it can be envisaged that IL-6 (MW 21kD) will have a sieving coefficient of at least 0.9.
13. Regarding claim 13, Kim discloses a membrane wherein the sieving coefficient for albumin in blood is below 0.05 (Table 1).
14. **Claim 2** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim in view of Deppisch et al., "Blood Material Interactions at the Surfaces of Membranes in Medical Applications" (Deppisch).
15. Kim fails to explicitly disclose the size of hydrophilic domains on the membrane surface are in the range of 20-50nm. However it is well known, as disclosed by Deppisch, that polyvinylpyrrolidone hemodialysis membranes such as those disclosed by Kim have hydrophilic domains in the range of 20-200 nm (Pg. 247, Col. 2, Para. 1)

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and that hydrophilic domains improve thrombogenicity (Pg. 248, col. 2, l. 1-4). Since, Deppisch recognizes hydrophilic domains as a result effective variable, it would have been obvious to a person having ordinary skill in the art to optimize the size of the domains as it has been held that it is not inventive to discover the optimum ranges by routine experimentation (MPEP 2144.05, Part II).

16. **Claims 11, 14-15, 29-31, and 33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim in view of Buck et al., US 4935141 (Buck) as evidenced by Gorsuch and Kagawa et al., EP 0568045 (Kagawa).

17. Regarding claims 11 and 29, Kim does not explicitly disclose the pore size in the separation layer. However, asymmetric hollow fiber membranes having pore sizes in the range of 20-40nm are well known in the art as disclosed by Buck. Buck teaches an asymmetric hollow fiber membrane (abstract and Claim 1) wherein the separation layer contains pore channels with a pore size of 20-40nm (Claim 2). Therefore, it can be envisaged that the membrane disclosed in Kim would have a pore size in the separation layer of about 20-40nm since it has been shown in the prior art that such pore sizes are effective in separating low molecular weight species such as toxic mediators from blood during dialysis treatments.

18. Furthermore, while Kim does not explicitly disclose the pore size of the separation layer, it would have been obvious to a routineer in the art to control the pore size in order to effect a separation efficiency, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (MPEP 2144.05, Section II, Part A).

19. Regarding claims 14-15 and 33, Buck further discloses a membrane having an outer layer, different from the finger-like structure and this outer layer is equated with applicant's fourth layer, as evidenced by the similarities between fig. 1B of Buck and fig. 4 of applicant's specification. It is presumed that the structure of Buck has the stated properties of an outer surface including a pore size of 0.5 to 3 micron, alternatively it would have been obvious to produce a membrane with a outer layer pore size in the range of 0.5 to 3 micron based on the teachings of Buck which has the same sponge-like and finger-like structure of layers and the same inner layer pore size, as evidenced

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by Kagawa. Kagawa discloses that outer surface layer has micropores with a 0.1-0.5 micron average pore diameter (Pg. 10, Lines 44-51).

20. Regarding claims 30-31, it is either inherent or would have been obvious to produce an outer sponge layer with the property of pore density in the range of 20,000 to 100,000 pores per mm², based on the similarity in structure of Buck as evidenced by Kagawa. Kagawa discloses the process conditions can be modified to optimize the outer surface structure using a spinning process whereby hollow fiber membranes having many micropores of relatively large diameter in their outer surface can be readily obtained. Kagawa presents a finding that one of ordinary skill in the art could optimize the process conditions to obtain the desired pore size and number of pores on the surface with a reasonable expectation of success.

21. Alternatively, although Buck does not appear to expressly disclose that this outer layer is the fourth layer, it would have been obvious to one having ordinary skill in the art to include a fourth layer as it has been held that mere duplication of parts has no patentable significance (MPEP 2144.04, Part VI). Including four layers in a hollow fiber membrane is well-known, as evidenced by Gorsuch. Gorsuch discloses four zones in a hollow fiber membrane (Fig. 1). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

22. Applicant's arguments with respect to claim 1 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1797

/DRB/
Dirk R. Bass